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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------------------|------------------|
| 10/075,615  | 02/15/2002  | Joseph C. Cauthen III | 8442.0002-02                    | 2841             |
| 22852   | 7590        | 03/06/2006            |                                 |                  |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER<br>LLP<br>901 NEW YORK AVENUE, NW<br>WASHINGTON, DC 20001-4413 |             |                       | EXAMINER<br>CHATTOPADHYAY, URMI |                  |
|   |             |                       | ART UNIT<br>3738                | PAPER NUMBER     |

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/075,615             | CAUTHEN, JOSEPH C.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Urmi Chattopadhyay     | 3738                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 February 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 and 14-21 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 18-21 is/are rejected.  
 7) Claim(s) 1-12 and 14-17 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on February 23, 2006 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/075,615 is acceptable and a RCE has been established. An action on the RCE follows.

### ***Response to Amendment***

2. The amendment filed February 23, 2006 has been entered. The change to claim 21 has been approved. Claim 22 has been canceled. All pending claims 1-12 and 14-21 are being considered for further examination on the merits.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 18, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (USPN 5,571,189, as cited in applicant's IDS).

Kuslich et al. disclose a therapeutic or prophylactic device for treating a spinal disc annulus having an aperture with all the elements of claim 21. See Figures 43-47 and columns 10-11, lines 59-9 for a device (120) comprising a biocompatible material for placement across an aperture (46) in an annulus (30) such that the material forms a bridge. Because the device (120)

is made from pericardium, it provides as a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the spinal disc annulus (30). The device (120) has a means (126) for acute securement. Applicant is reminded that in a product claim, such as claim 21, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The patch device (120) of Kuslich is structurally capable of being placed in an aperture that is appropriately sized to receive the device. Also, the means (126) for acute securement is structurally capable of acutely securing the device (120) to the disc annulus (30) if the device (120) were rotated ninety degrees from the orientation shown in the figures.

Claim 18, see column 10, lines 63-65 for the device (120) being made from a biocompatible material.

Claim 20, see column 10, lines 63-65 for the device (120) being made from pericardium. Because pericardium provides as a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the spinal disc annulus, it facilitates the regeneration of the disc tissue.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (USPN 3,867,728, as cited in applicant's IDS).

Stubstad et al. disclose an embodiment of a therapeutic or prophylactic device for treating a spinal disc annulus having an aperture with all the elements of claim 21, but are silent to the embodiment of the device having means for acute securement of the device to the disc annulus. See Figures 20-22 and column 3, lines 12-21 for a device (100) comprising a biocompatible material (columns 12-13, lines 61-5) for placement in and across the aperture (column 14, lines 40-42) such that the material forms a bridge providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the spinal disc annulus (column 13, lines 19-23). In a different embodiment disclosed by Stubstad et al. and shown in Figures 23-24, a device (120) includes a means for acute securement in the form of sutures, wherein the device (120) is sutured to one of the adjacent vertebrae or "other available tissue" in order to stabilize the device. See column 14, lines 48-50. Because the only "other available tissue" for suturing besides the adjacent vertebrae would be the annulus, Stubstad et al. is clearly suggesting an embodiment wherein the device (120) is sutured to the annulus in order to stabilize the device. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of the device shown in Figures 23-24 to modify the device shown in Figures 20-22 by including means for acute securement in the form of sutures and suturing the device (100) to the annulus in order to stabilize the device.

Claim 18, see columns 12-13, lines 61-5 for the device (100) being made from a biocompatible material.

Claim 19, see column 12, line 64 for the device (100) comprising a biocompatible fiber mesh.

Claim 20, see column 13, lines 19-23 for the open-pore tissue-receptive surface that promotes the growth of tissue being a material that facilitates regeneration of disc tissue.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 21 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,997,956. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and the patent claim a device of a material for placement in and across an aperture in an annulus,

and for providing a platform/scaffold for a traverse of cells across the aperture. The patent claim limitation of a fixation element for attaching the device to the annulus meets the application claim limitation of the device having means for acute securement of the device to the disc annulus. It would have been obvious to one of ordinary skill in the art to make the device of the patent of biocompatible material.

*Allowable Subject Matter*

9. Claims 1-12 and 14-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*

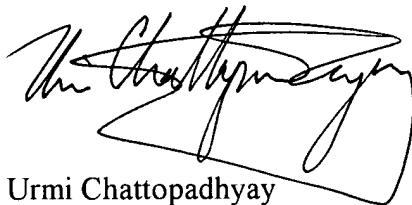
10. Applicant's arguments with respect to claims 1-12 and 14-21 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

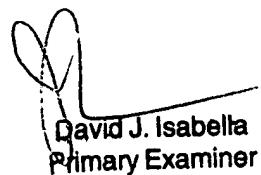
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella  
Primary Examiner